REMARKS

Claims 56, 69, 71, 107, 110 and 112-130 are pending in this application for the Examiner's review and consideration. No new matter has been added.

I. The Rejection under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 56, 69, 71, 107, 110, 112 and 113-130 are rejected under 35 U.S.C. § 103(a) as obvious over PCT International Publication Number WO 91/19726 to Piantadosi ("Piantadosi") for reasons set forth on pages 2-3 of the Office Action. Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that the legally required teaching or suggestion of each and every element of the claims is not disclosed in the cited reference. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re O'Farrell,* 853 F.2d 894 (Fed. Cir. 1988); *In re Royka*, 409 F.2d 981, 180 USPQ 580 (CCPA 1974); and M.P.E.P. § 2143.03. Furthermore, Applicants reiterate that in asserting an obviousness rejection of a species when the prior art teaches a genus, the fact that a claimed species or subgenus is encompassed by a prior art genus is insufficient by itself to establish a *prima facie* case of obviousness. *See In re Baird,* 16 F.3d 380, 382 (Fed. Cir. 1994); and M.P.E.P. § 2144.08. In addition, some motivation to select the claimed species must be taught by the prior art. M.P.E.P. § 2144.08. (emphasis added).

The Examiner calculates that the number of possible compounds disclosed by the Piantadosi is "only 400." Applicants respectfully disagree with this calculation. However, even assuming *arguendo* Piantadosi did in fact disclose "only 400" compounds, such a disclosure nevertheless fails to render the pending claims, which recite a method of treating a viral infection with a single compound or salt thereof, obvious.

To narrow the genus disclosed by Piantadosi in order to contrive a *prima facia* case of obviousness, the Examiner improperly uses the pending claims as a blue print and then picks and chooses from the substituents of the genus disclosed by Piantadosi. As the Examiner is aware, it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). Indeed, it would be virtually impossible to pick either of the compounds recited by the pending claims based on

the disclosure of Piantadosi without the aid of hindsight. Even when picking and choosing substituents from preferred embodiments in Piantadosi, the reference fails to suggest a 3-dodecanamido or a 3-dodecyloxy group as contained by the compounds in the pending claims. Indeed, Piantadosi discloses that R^1 is C10-C20 saturated or unsaturated alkyl containing not more than three double bonds, and R^2 is H or C1-C20 saturated or unsaturated alkyl containing not more than three double bonds.

Piantadosi teaches ether lipid-nucleosides, wherein each of these ether lipid nucleosides is encompassed by Formulas I, II and III. *See* Piantadosi at page 2, line 13 through page 6, line 7. Piantadosi does not render independent claims 56 or 107 obvious since Piantadosi does not provide the legally required motivation to modify the disclosure of the reference to teach the claimed invention. The Examiner has stated that Piantadosi discloses "only 400" compounds; however, in no instance does Piantadosi disclose or suggest the method comprising 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine or a pharmaceutical salt thereof or 3'-azido-3'-deoxy-5'-(3-dodecyloxy-2-decyloxypropyl)-phosphothymidine, or a pharmaceutical salt thereof.

Indeed, there is no motivation to select the individual substituents from the generic disclosure of Piantadosi to thereby suggest a method comprising 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine or 3'-azido-3'-deoxy-5'-(3-dodecyloxy -2-decyloxypropyl)-phosphothymidine or a salt thereof without using the pending claims as a blue print to pick and choose the claim elements from the cited reference.

Applicants emphasize, the CCPA cautioned that "it is impermissible within the framework of 35 U.S.C. § 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau,* 353 F.2d 238 (CCPA 1965*)*. In addition, in *In re Wright* (1989), the Office's attempt to show a suggestion of the claimed invention consisted of taking statements wholly out of context and giving them meanings they would not have had to one skilled in the art having no knowledge of applicant's invention, or for that matter to anyone else who can read the specification with understanding

Applicants respectfully submit that one of ordinary skill in the art simply would not have a reasonable expectation that 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine, 3'-azido-3'-deoxy-5'-(3-dodecyloxy -2-decyloxypropyl)-phosphothymidine or a pharmaceutical salt thereof is effective in combating HIV-1, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenze virus based on the disclosure of Piantadosi.

Since claims 69 and 71, 110-130 depend from either claim 56 or 107 respectively and include all the features of claim 56 and 107, these claims are not rendered obvious for at least the same reasons that the independent claims are not rendered obvious.

For the above reasons, Applicant respectfully requests that the rejection of claims 56, 69, 71, 107, 110, and 112-130 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

II. The Double Patenting Rejection Should be Withdrawn

The Examiner rejected claims 56, 69, 71, 107, 110, 111, and 113-130 for obviousness-type double patenting as being obvious over claims 1-3, 8, 9, 33-36 and 41-43 of U.S. Patent No. 6,030,960 ("the '960 patent).

Applicants submit herewith a Terminal Disclaimer disclaiming the terminal part of any patent granted on the above identified application, which would extend beyond the expiration date of U.S. Patent No. 6,030,960, subject to the language included in the disclaimer. For the above reason, Applicants respectfully request that the double patenting rejection be reconsidered and withdrawn.

III. The Rejection under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

Claims 120, 121, 129, and 130 are rejected under 35 U.S.C. § 112, first paragraph, for reasons set fourth on page 4 of the Office Action. Specifically, the office action alleges that the claims fail to comply with the written description requirement because the claims include dosages not described in the specification with respect to the two species claimed. Applicants respectfully traverse the rejection.

As the Examiner is aware, "[a]ccording to 35 U.S.C. § 112, ¶ 1, a patent specification must contain a written description of the invention sufficient to 'allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Johnson*

Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985 (Fed. Cir. 1999). The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 966 (Fed. Cir. 2002).

The specification discloses:

> Exemplary compounds of Formula I include l-dodecanamido-2decyloxypropyl-3- phosphocholine (CP-128), 1-dodecanamido-2octyloxypropyl-3-phosphocholine (CP-130), 1-dodecanamido-2dodecyloxypropyl-3-phosphocholine (CP-131), and l-dodecyloxy-2decyloxypropyl-3-phosphocholine (CP-129). These compounds of Formula 1 can be synthesized according to the procedures set forth in Examples 1 and 2 below. Other compounds of Formula I can be synthesized using the same method with the appropriate reagents substituted for those listed.

Moreover, Applicants respectfully submit that the application at page 18, lines 11-17, as filed discloses:

> The compounds of Formulas I, II, III and IV are administered in an amount sufficient to combat viral infection. The dose can vary depending on the compound selected for administration, the subject, the route of administration, and other factors. Preferably, the compound is administered in an amount of at least 0.1 ng/kg, 1 ng/kg, 0.001 μg/kg or more, and is administered in an amount no greater than 0.1 g/kg, 0.01 g/kg, 1 mg/kg, or less.

(*See* specification at page 18, lines 11-17).

Applicants further submit that Examples 5 and 6 on pages 21-23 teach the preparation of 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine and of 3'-azido-3'-deoxy-5'-(3-dodecyloxy-2-decyloxypropyl)-phosphothymidine, which compounds are encompassed by Formula I. Because the Applicant stated that the "compound is administered in an amount of at least 0.1 ng/kg, 1 ng/kg, 0.001 μg/kg or more, and is administered in an amount no greater than 0.1 g/kg, 0.01 g/kg, 1 mg/kg, or less," one of ordinary skill in the art would clearly understand that the inventors were in possession of the claimed invention. Indeed, the fact that Applicants disclose *ipsis verbis* support for the

claimed dosages further supports the compliance of the specification with the written description requirement.

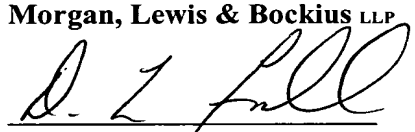
Applicants respectfully request that the rejection of claims 120, 121, 129, and 130 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. Conclusions

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Please charge the Terminal Disclaimer fee under 37 C.F.R. § 1.20(d) of $130.00 to Deposit Account No. 50-0310. Aside from the Terminal Disclaimer fee, no additional fee is believed to be due with this Amendment. Should any additional fee be required, however, please charge such fee to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310.

Respectfully submitted,
Morgan, Lewis & Bockius LLP



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